IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION

IN RE: ETHICON, INC. PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION	**Master File No. 2:12-MD-02327** **MDL No. 2327**
THIS DOCUMENT RELATES TO: ETHICON WAVE 11 CASE *Welch, et al. v. Ethicon, Inc., et al.*, 2:12-cv-08677, and all future Wave cases	**JOSEPH R. GOODWIN** **U.S. DISTRICT JUDGE**

DEFENDANTS' RESPONSE IN OPPOSITION TO PLAINTIFFS' *DAUBERT* MOTION TO EXCLUDE THE TVT GENERAL CAUSATION OPINIONS AND TESTIMONY OF BRUCE S. KAHN, M.D.

Defendants Ethicon, Inc. and Johnson & Johnson (collectively, "Defendants") submit this response in opposition to Plaintiffs' *Daubert* motion to exclude the TVT general causation opinions and testimony of Bruce S. Kahn, M.D. (Doc. Nos. 8565 – Pls.' Mot.; 8566 – Pls.' Mem. in Supp.).

INTRODUCTION

Plaintiffs seek to exclude the TVT general causation opinions of Ethicon's designated general obstetrics & gynecology expert, Dr. Bruce S. Kahn ("Dr. Kahn"). Dr. Kahn is board certified in Obstetrics & Gynecology and was among the first group of surgeons in the country to attain a sub-specialty certification in Female Pelvic Medicine & Reconstructive Surgery (Urogynecology) in 2013. Ex. A: General Expert Report of Bruce S. Kahn, M.D. ("Kahn Report"), at 2; Ex. B: Bruce S. Kahn, M.D. 8/1/19 Dep. Tr. ("Kahn Dep."), at 25:9-26:19. Dr. Kahn is a fellow of the American College of Obstetrician-Gynecologists (ACOG) and a member

of the American Association of Gynecologic Laparoscopists (AAGL) and the American Urogynecologic Society (AUGS). Ex. A: Kahn Report, at 2.

Dr. Kahn practices in San Diego, California, where he has worked in the Division of Gynecologic Surgery at Scripps Clinic since 1999. Ex. A: Kahn Report, at 2. Prior to that, Dr. Kahn was commissioned as a Lieutenant Commander in the U.S. Naval Reserve and served as a Staff Obstetrician-Gynecologist and Clinical Instructor at the Naval Medical Center San Diego from 1996-1998. *Id.* Dr. Kahn then served as an Assistant Clinical Professor in the Department of Reproductive Medicine at the University of California San Diego from 1998-1999, before joining the Division of Gynecologic Surgery at Scripps Clinic. *Id.*

While Dr. Kahn's practice is focused on clinical patient care, Dr. Kahn is also involved in significant clinical teaching and research. Ex. A: Kahn Report, at 2. Dr. Kahn created and continues to direct a rotation at Scripps Clinic for residents from the Department of Obstetrics and Gynecology at the Naval Medical Center San Diego. *Id.* He also holds a faculty appointment as an Adjunct Clinical Professor in the Department of Obstetrics & Gynecology at the Uniformed Services University of the Health Sciences in Bethesda, Maryland. *Id.* He lectures nationally and internationally on topics related to gynecology and has been involved in several clinical research projects involving the treatment of pelvic organ prolapse, urinary incontinence, and pelvic pain problems including interstitial cystitis and endometriosis. *Id.*

With more than two decades of experience in the field, Dr. Kahn has performed a number of different surgical procedures to treat stress urinary incontinence, including the Kelly plication, Marshall-Marchetti-Krantz and Burch colposuspension procedures, as well as autologous fascial slings and needle suspension (Pereyra) procedures. Ex. A: Kahn Report, at 2. However, those procedures were replaced in Dr. Kahn's practice in approximately 2000 when the TVT mid-

urethral sling was introduced. Ex. A: Kahn Report, at 2; Ex. B: Kahn Dep., at 38:4-39:23. In total, Dr. Kahn has implanted approximately 2,000 mid-urethral slings and approximately 200 TVT devices. Ex. A: Kahn Report, at 22; Ex. B: Kahn Dep., at 48:15-49:5.

Dr. Kahn intends to offer opinions generally addressing the utility and safety of Defendants' TVT device. Dr. Kahn has performed thousands of retropubic mid-urethral sling implantation procedures utilizing polypropylene mesh devices, including the TVT, and is more than qualified to offer the opinions in his general causation report relating to TVT. His opinions are based upon his education, medical training, clinical experience, extensive review of medical literature, position statements, guidelines, practice patterns, curricula, and various other materials reflected in his reliance list. Ex. C: Reliance List. Although Plaintiffs have challenged certain aspects of Dr. Kahn's opinions, as set forth below, he is qualified to opine on these topics, and his opinions are supported by a reliable methodology.

ARGUMENT

Ethicon incorporates by reference the standard of review for *Daubert* motions as articulated by the Court in *Huskey v. Ethicon, Inc.*, 29 F. Supp. 3d 691, 701 (S.D.W. Va. 2014).

I. Dr. Kahn Is Qualified to Render Opinions Regarding the Safety and Efficacy of the TVT Device.

Plaintiffs' assertion that Dr. Kahn is unqualified to offer expert opinion testimony regarding the safety and efficacy of the TVT lacks merit. Plaintiffs argue first that the Court should preclude Dr. Kahn from testifying as a general causation expert regarding the TVT because he has not implanted a TVT device for the treatment of stress urinary incontinence since 2005. Pls.' Mem. in Supp. (Doc. No. 8566), at 5. Plaintiffs claim that Dr. Kahn, therefore, lacks the requisite knowledge, experience and understanding of the TVT device. *Id.*

Plaintiffs do not call into question Dr. Kahn's education, training or experience regarding the treatment of stress urinary incontinence or the use of polypropylene mesh mid-urethral slings in general. Instead, Plaintiffs focus solely on the fact that Dr. Kahn transitioned from utilizing the TVT device in his own practice in approximately 2005, and began using a similar device manufactured by Boston Scientific. Plaintiffs' argument misses the mark. As mentioned above, Dr. Kahn has implanted approximately 2,000 polypropylene mesh retropubic mid-urethral slings during his approximately two decades of practice, with approximately 200 of those involving the implantation of the TVT device. Ex. A.: Kahn Report, at 22; Ex. B: Kahn Dep., at 48:15-49:5. Dr. Kahn testified that the Boston Scientific sling that he transitioned to "was essentially the same thing" as the TVT, but he perceived a couple of advantages to the Boston Scientific sling. Ex. B: Kahn Dep., at 47:15-48:4. He specifically testified as follows:

> Q: Doctor, why don't you utilize the TVT product in your practice anymore?
>
> A: That's a good question.
>
> The reason I switched from using the TVT device to the Boston Scientific product had nothing to do with how well or how safe that the TVT was. I think it was safe at that time. I think it remains to be a safe device.
>
> The reason I switched was the Boston Scientific product had a -- at least one little advantage for putting it in that made the procedure actually a little bit easier to complete.
> . . .
>
> The procedure is essentially the same. . . . They -- I think both products work well. The long-term data for both products is it works well. There's no complications with it, so I never had any issues with the mesh itself.

Id. at 61:14-64:14.

Contrary to Plaintiffs' argument, Dr. Kahn does not rely strictly on "his experience and observations strictly in a clinical setting." Pls.' Mem. in Supp. (Doc. No. 8566), at 5. Instead, Dr. Kahn's report details not only his extensive experience with the implantation of mesh slings

like the TVT device, but also his extensive review of the relevant literature relating to the TVT device. Ex. A: Kahn Report, at 2-3, 6-15, 22. Moreover, Dr. Kahn testified that even after he transitioned to the use of the Boston Scientific device in his practice, he continued to keep up with medical literature about the treatment of stress urinary incontinence and the TVT device, including reviewing long term studies, comparative studies, and meta-analyses. Ex. B: Kahn Dep., at 68:20-69:7. As set forth in the Introduction section above, Dr. Kahn is imminently qualified to provide expert opinions addressing the utility and safety of the TVT device, and he has drawn not only on his clinical and research experience, but also on his extensive review of relevant literature as detailed in his Report, in formulating his opinions. If Plaintiffs wish to do so, they may use cross-examination at trial to show Dr. Kahn's purported lack of familiarity with the TVT device. However, the Court should deny Plaintiffs' motion to exclude Dr. Kahn's general causation opinions in their entirety based on a purported lack of qualification.

II. Dr. Kahn Is Qualified to Offer Opinions Regarding How the TVT Interacts Within the Body Based on His Extensive Clinical Experience and Review of the Medical Literature.

Plaintiffs next assert that Dr. Kahn is unqualified to offer opinion testimony regarding the biocompatibility of the TVT, Prolene or polypropylene, arguing that Dr. Kahn has no experience in researching or investigating the biocompatibility of the TVT or the materials used in the device, and instead relies solely on his clinical experience. Pls.' Mem. in Supp. (Doc. No. 8566), at 6-7. Plaintiffs attack a straw man. Dr. Kahn explained (multiple times) during his deposition that his expertise on the interaction of the TVT within the body is based on his nearly two decades of clinical experience, as well as his research, attendance at meetings, and his extensive review of high-level scientific literature. Ex. B: Kahn Dep., at 127:23-133:25.

In a transparent attempt to downplay Dr. Kahn's education, training, and extensive practical experience relating to the interaction of the TVT, Prolene and polypropylene within the body, Plaintiffs notably exclude from their citation to Dr. Kahn's deposition testimony any mention of how Dr. Kahn's clinical experience forms a basis for his opinions, as well as Dr. Kahn's testimony regarding his extensive review of the medical literature and his training relating to the biocompatibility of medical products, which dates back to his residency:

> A: . . . . And so you have to understand it really goes hand in hand. If you don't have an understanding of biocompatibility of something you're putting in a patient if you're not following them clinically, then it -- you wouldn't be performing your duties as a physician well.
>
> Q: So is your opinion about the biocompatibility of TVT solely based on your experience as a clinician?
> . . .
>
> A: No. Because in addition to that, in developing my opinion here, I've been provided a lot of additional information to -- and found additional information on my own to develop the opinions I've provided here.
> . . .
>
> Q: Do you have any specific training in the -- in biocompatibility of products, medical products?
> . . .
>
> A: I -- I think so. I think going back to my residence training. I mean, that's -- it goes back that far. I think that there is a significant amount of biocompatibility training involved in taking care of patients and putting these implants in.

Ex. B: Kahn Dep., at 129:3-17; 132:2-11.

Dr. Kahn's opinions about the safety and efficacy of the TVT necessarily incorporate his clinical observations, and his knowledge gleaned from the medical literature, about the biocompatibility of the materials used in the TVT. Beyond that, Dr. Kahn does not purport to opine on the details of the chemical composition and properties of these materials. If Plaintiffs wish to do so, they may cross-examine Dr. Kahn at trial to demonstrate his purported lack of

familiarity with specific details regarding the biocompatibility of the TVT, Prolene or polypropylene. Their challenge, however, does not render Dr. Kahn's opinions generally inadmissible.

In fact, this Court has previously found that clinicians experienced with mesh can offer opinions about "how the product reacts within the body," and it should do the same here. *Winebarger v. Boston Sci. Corp.*, No. 2:13-cv-28892, 2015 WL 1887222, at *26 (S.D.W. Va. Apr. 24, 2015); *see also Tyree v. Boston Sci. Corp.*, 54 F. Supp. 3d 501, 585 (S.D.W. Va. 2014) (finding urogynecologist who has performed almost 3,000 sling procedures over the last twenty years qualified to testify that mesh does not shrink, contract, degrade, or cause systemic infection); *Huskey v. Ethicon, Inc.*, 29 F. Supp. 3d 691, 734 (S.D.W. Va. 2014) (finding Dr. Johnson qualified to opine as to mesh degradation); *Carlson v. Boston Sci. Corp.*, No. 2:13-CV-5475, 2015 WL 1931311, at *9–*19 (S.D.W. Va. Apr. 28, 2015) (finding Dr. Galloway's clinical experience and review of the scientific literature adequately qualified him to opine on polypropylene, including its degradation, leaching, shrinkage, and contraction); *In re: Ethicon, Inc.*, No. 2:12-MD-02327, 2016 WL 4536885, at *3 (S.D.W. Va. Aug. 30, 2016) (holding that Dr. Margolis, a urogynecologist, was qualified to testify regarding biomaterial properties including mesh reaction to and effect on the human body).

In sum, Dr. Kahn's opinions are drawn from his own extensive clinical experience actually treating thousands of women with mesh slings like the TVT, as well as his thorough research and review of high-level scientific literature. The Court should deny Plaintiffs' motion on this ground.

III. Dr. Kahn Is Competent to Testify About Alleged Degradation and Fraying and His Opinions Are Reliable.

There is no merit to Plaintiffs' argument that Dr. Kahn may not testify about alleged degradation and fraying of the TVT. Plaintiffs first claim that Dr. Kahn is not qualified to testify on alleged degradation and fraying of the TVT because "he has no experience in testing, examining, or researching the TVT mesh." Pls.' Mem. in Supp. (Doc. No. 8566), at 8. This statement is patently false. Dr. Kahn's Report and deposition testimony set out in great detail Dr. Kahn's extensive clinical experience utilizing, examining and researching polypropylene mesh slings like the TVT. Dr. Kahn is qualified to opine about degradation and fraying based on his significant clinical experience (in which he has not observed any clinically meaningful degradation or fraying), Ex. B: Kahn Dep., at 91:21-92:20; 99:12-16; 100:1-5; 100:23-101:8; 101:16-102:10, as well as his extensive review of scientific literature—including literature that Plaintiffs' experts in these cases have cited and relied upon. Ex. B: Kahn Dep., at 91:21-92:20; Ex. C: Reliance List.

In these MDLs, the Court has allowed urologists and gynecologists with similar qualifications as Dr. Kahn to testify about alleged degradation and fraying. For instance, in *Trevino v. Boston Sci. Corp.*, No. 2:13-cv-01617, 2016 WL 2939521 (S.D.W. Va. May 19, 2016), the plaintiff argued that Dr. Michael Douso, a urogynecologist, was not qualified to testify about the physical properties of mesh and to offer opinions about degradation and similar topics because he was not a biomaterials or polymer science expert. In rejecting this challenge, the Court stated as follows:

> Dr. Douso is a practicing urogynecologist, and he is board-certified in obstetrics and gynecology. He has extensive experience with BSC's products for treating SUI and POP, including use of the Prefyx and Uphold mesh sling devices. Dr. Douso has had extensive experience teaching minimally invasive surgical techniques and procedures to physicians across the United States, including

> implantation of the defendant's polypropylene mesh devices. Simply because Dr. Douso is not an engineer, chemist, or biomechanical expert does not render him unqualified to testify that he has not experienced mesh degradation, contraction, or a foreign body response in his practice. "One knowledgeable about a particular subject need not be precisely informed about all details of the issues raised in order to offer an [expert] opinion." *Thomas J. Kline, Inc.*, 878 F.2d at 799. I **FIND** that Dr. Douso's extensive experience qualifies him to testify that he has not experienced certain alleged physical properties in the defendant's Uphold and Prefyx devices.

Id. at *44 (internal citations omitted); *see also id.* at *5 (finding that urologist Niall Galloway's "clinical experience and review of the scientific literature adequately qualify him to opine on polypropylene, including its degradation, leaching, shrinkage and contraction"); *id.* at *33 (allowing testimony of defense expert Patrick Culligan, M.D.); *Huskey,* 29 F. Supp. 3d at 706-07, 735 (rejecting similar challenges to plaintiff expert Bruce Rosenzweig, M.D., and defense expert urogynecologist Harry Johnson, M.D.); *Tyree,* 54 F. Supp. 3d at 550, 585 (rejecting similar challenge of plaintiff expert Donald Ostergard, M.D. and defense expert Lonny Green, M.D.); *Jones v. Bard, Inc.*, No. 2:11–cv–00114, [Doc. 391], pp. 6–9.

Moreover, Plaintiffs make much of the fact that Dr. Kahn testified during his deposition that he was not intimately familiar with the concepts of mesh degradation or fraying before reviewing the reports of Plaintiffs' experts and literature they have cited in this litigation, claiming that this testimony renders him unqualified and his opinions unreliable. However, as Dr. Kahn testified, it is the fact that *"[he] hadn't had any clinical problems"* with degradation or fraying during his nearly two decades implanting polypropylene mesh slings, including the TVT, that lends support for his opinion that alleged degradation and fraying of the mesh is not of clinical significance. Ex. B: Kahn Dep., at 91:21-92:20; *see also id.* at 99:12-16; 100:1-5 ("Q: Have you ever done any studies on the fraying of mesh or polypropylene, Doctor? A: I guess you could say I've done a pretty good study for 20, 25 years with my own patients, and I have

not found that to be a problem. . . . Q: Doctor, have you ever -- A: But again, I want to go back to adding that, you known, it's something that I've paid attention to in my clinical care of patients, and it just hasn't been an issue."); 100:23-101:8 ("Q: Were you looking for fraying of the TVT product when you began implanting it in 2000? A: Again, my answer would be that I was looking for any complications that my patients may have. Fraying was not something that -- unless I was looking for it, but if fraying were causing problems for my patients, I certainly would be interested in looking at that, and I was looking at that carefully to see if my patients were having any problems with their surgery."); 101:16-102:10 ("Q: Okay. Were you looking specifically for fraying of the mesh when you began implanting it in 2000? A: I was looking for problems -- any problems my patients might be having with surgery. Q: Did you know to look for fraying of the TVT product? A: I was looking for their clinical outcomes. . . . Q: Doctor, were you looking for fraying of the TVT product in 2000 when you began implanting it in your patients? A: I was looking for any problems they might have, including something like fraying that I may not have been aware of. But again, I was looking for any clinical problems they might be having."). Dr. Kahn's opinions are further bolstered by his review of Level 1 long-term studies, RCTs, systematic reviews, meta-analyses, and Cochrane reviews demonstrating the safety of polypropylene mesh and that the mesh is not degrading or fraying. *See, e.g.*, Ex. A: Kahn Report, at 6-15, Ex. C: Reliance List.

Dr. Kahn is, therefore, qualified to offer expert testimony about alleged degradation and fraying of the TVT and his opinions are supported by a reliable methodology. Plaintiffs' motion on this topic should be denied.

IV. Dr. Kahn Is Qualified to Testify Regarding the Adequacy of Warnings and His Opinions Are Reliable.

Dr. Kahn has opined on the completeness and accuracy of the TVT IFU warnings from a clinical perspective based on his knowledge, review of published medical literature, and his clinical experience with the device. *See* Ex. A: Kahn Report, at 22-23. Plaintiffs first argue, in essence, that Dr. Kahn is not qualified to opine on the adequacy of the IFUs because he is not a warnings expert. Pls.' Mem. in Supp. (Doc. No. 8566), at 12 ("Dr. Kahn has not articulated any knowledge of the FDA regulations concerning warnings or other contents of an IFU. He also has not explained any experience with drafting warnings or other contents of an IFU."). Ethicon concedes that Dr. Kahn is not a regulatory expert and will not opine on warnings from that perspective.

However, the Court should allow Dr. Kahn to provide the same type of warnings opinions that it has allowed other experts to provide in this litigation. Dr. Kahn's qualifications are no different than all of the other pelvic surgeon experts in this litigation whom the Court has allowed to testify, and consistent with the Court's prior rulings Dr. Kahn should be allowed to testify "about the specific risks of implanting mesh and whether those risks appeared on the relevant IFU." *In re: Ethicon Inc. Pelvic Repair Sys. Prod. Liab. Litig.*, MDL No. 2327, 2016 WL 4582231, at *3 (S.D.W. Va. Sept. 1, 2016). Dr. Kahn's Report details his extensive experience with the implantation of mesh slings like the TVT device, as well as his extensive review of the relevant literature relating to the TVT device. Ex. A: Kahn Report, at 2-3, 6-15, 22; *see also* Ex. C: Reliance List.

Dr. Kahn also seeks to testify that the complications that Plaintiffs allege should have been in the IFU: (a) are risks that a pelvic surgeon would already know, and therefore, need not be warned about; (b) are not genuine complications; or (c) are not attributable to the device. As

it relates to the latter two categories, Dr. Kahn's Report shows that his opinions are based on his extensive clinical experience, as well as his thorough critique of scientific literature. Ex. A: Kahn Report, at 17-22; Ex. C: Reliance List; *see also Huskey*, 29 F. Supp. 3d at 734-35 (allowing Dr. Johnson to testify about evidence of absence because his opinions were also based on medical literature); *Carlson*, 2015 WL 1931311, at *12. The Court should also allow Dr. Kahn to testify about what risks are commonly known by surgeons, and therefore, need not be included in the IFU. Dr. Kahn, as an experienced clinician, is well qualified to testify about complications that are "common knowledge among licensed pelvic floor surgeons," such that they need not be included in an IFU. Ex. A: Kahn Report, at 22. The Court has expressed no opinion about expert testimony regarding "whether certain risks were common knowledge," and therefore has not precluded this expert testimony. *See, e.g.*, *In re: Ethicon Inc.*, 2016 WL 4582231, at *3 n.2 ("The plaintiffs' Motion focuses on whether Dr. Woods is qualified to offer expert testimony about what should be included in or what may be excluded from an IFU. So I offer no opinion on whether Dr. Woods may testify about whether certain risks were common knowledge."); *In re: Ethicon Inc. Pelvic Repair Sys. Prod. Liab. Litig.*, MDL No. 2327, 2016 WL 4557036, at *3 n.2 (S.D.W. Va. Aug. 31, 2016) (same, with respect to Dr. Drolet); *In re: Ethicon, Inc. Pelvic Repair Sys. Prod. Liab. Litig.*, MDL No. 2327, 2016 WL 4536875, at *4 n.2 (S.D.W. Va. Aug. 30, 2016) (same, with respect to Dr. Serels); *In re: Ethicon, Inc. Pelvic Repair Sys. Prod. Liab. Litig.*, MDL No. 2327, 2016 WL 4542054, at *3 n.2 (S.D.W. Va. Aug. 30, 2016) (same, with respect to Dr. Elser); *In re: Ethicon, Inc. Pelvic Repair Sys. Prod. Liab. Litig.*, MDL No. 2327, 2016 WL 4536872, at *3 n.2 (S.D.W. Va. Aug. 30, 2016) (same, with respect to Dr. Sepulveda-Toro); *In re: Ethicon, Inc. Pelvic Repair Sys. Prod. Liab. Litig.*, MDL No. 2327, 2016 WL 4493364, at *4 n.2 (S.D.W. Va. Aug. 25, 2016) (same, with respect to Dr. Toglia); *In re: Ethicon, Inc. Pelvic Repair*

Sys. Prod. Liab. Litig., MDL No. 2327, 2016 WL 4493681, at *3 n.2 (S.D.W. Va. Aug. 25, 2016) (same, with respect to Dr. Pramudji).

Other courts have recognized that expert testimony regarding the state of knowledge of the anticipated user is appropriate, indeed required, in warnings cases. *Flannery v. Bauermesiter*, No. CIV. A. 06-399S, 2008 WL 77723, at *2 (D.R.I. Jan. 4, 2008) (granting summary judgment in part based on testimony from the defendants' experts as to what "is known within the correctional medical community"); *Waterhouse v. R.J. Reynolds Tobacco Co.*, 368 F. Supp. 2d 432, 437 (D. Md. 2005), *aff'd*, 162 F. App'x 231 (4th Cir. 2006) ("[E]xpert testimony is required with respect to the state of common knowledge of smoking hazards during the smoking career of a plaintiff and that that testimony must be rendered by competent experts."); *Cruz-Vargas v. R.J. Reynolds Tobacco Co.*, 348 F.3d 271, 277 (1st Cir. 2003) (testimony regarding common knowledge is critical in failure to warn cases, and expert opinion concerning knowledge of average consumer was appropriate and relevant). The law imposes no duty to warn sophisticated users of products with respect to risks that the sophisticated users already know or should know. *See, e.g.*, Restatement (Third) of Torts: Product Liability §2 cmt. j (1998); Restatement (Second) of the Law of Torts §402A cmt. j; American Law of Product Liability 3d § 32:69 (2016); *Willis v. Raymark Indus., Inc.*, 905 F.2d 793, 797 (4th Cir. 1990). In fact, 21 CFR § 801.109(c) states there is no duty to warn if "the article is a device for which the hazards, warnings and other information are commonly known to practitioners licensed by law to use the device."

This is an objective test not dependent on the knowledge of the individual surgeon, and Dr. Kahn is certainly competent to share his opinions about what risks should be obvious to surgeons who use the devices and how an average clinician would construe the IFU. Indeed, Ethicon writes its IFUs for pelvic floor surgeons like Dr. Kahn. Under the learned intermediary

doctrine, such surgeons are the ones who must be adequately warned. If Plaintiffs intend to argue at trial that Ethicon's IFUs failed to disclose certain risks, then it is only fair that Ethicon be allowed to defend itself by demonstrating that those risks were obvious to the users of the product (pelvic surgeons and urologists), and therefore, did not need to be included in the IFUs in accordance with the aforementioned law.

Dr. Kahn is well qualified to testify regarding the risks that are within the common knowledge of surgeons who perform pelvic surgeries as set forth in detail in his CV and Report. *See* Ex. A: Kahn Report, at 2-3, 22; Ex. D: Bruce S. Kahn, M.D. CV. In addition, Dr. Kahn relies on his review of complications reported in the medical literature, statements of leading medical societies, discussions with other surgeons, and general knowledge as a pelvic-floor surgeon in reaching his opinions. As a practicing surgeon who went through years of medical training, who has extensive clinical experience with pelvic floor surgeries, who teaches other physicians about these surgeries, and who keeps up with the medical literature, Dr. Kahn is uniquely qualified to offer opinions about what is within the common knowledge of physicians who perform pelvic floor surgeries. Indeed, only a physician with such training and experience *could* testify as to common knowledge of surgeons who perform pelvic surgeries. Because Dr. Kahn has the qualifications and requisite foundation, he may offer his opinions about this topic.

Ethicon respectfully requests that this Court deny Plaintiffs' motion to the extent it seeks to exclude Dr. Kahn's testimony regarding the common knowledge of physicians regarding risks associated with pelvic floor surgery, and risks of implanting mesh and whether they were included in the IFUs.

V. Dr. Kahn's Opinions Regarding Pain, Erosion and Exposure, and Urinary Problems Are Supported by a Reliable Methodology.

Plaintiffs seek the exclusion of Dr. Kahn's causation opinions regarding pain, erosion, exposure, and urinary problems arguing generally that the opinions are unsupported and unreliable. However, Dr. Kahn's opinions that pelvic pain, vaginal pain, dyspareunia, erosion or exposure, and urinary problems are not attributable to any alleged defect or inherent characteristic of the TVT polypropylene mesh device are supported by Dr. Kahn's decades of clinical experience and his extensive review of the medical literature, as set forth in detail in his Report and Reliance List. As Dr. Kahn explained during his deposition as it relates specifically to pain and dyspareunia: "But . . . the underlying statement there is that pain is a risk of surgery, any vaginal surgery, whether it be a sling or any other repair, there is a risk of dyspareunia." Ex. B: Kahn Dep., at 150:13-16. Likewise, as it relates to erosion or exposure and urinary problems, Dr. Kahn opines that these alleged complications are not attributable to any specific defect in the TVT itself, as alleged by Plaintiffs, but instead are well-known risks of various surgical procedures to treat stress urinary incontinence. Ex. A: Kahn Report, at 18-19. Contrary to Plaintiffs' baseless and conclusory assertion, Dr. Kahn's opinions are based on his two decades of clinical experience, as well as his research and his extensive review of high-level scientific literature.

Based on this, the Court should allow Dr. Kahn to testify regarding the lack of causation relating to complaints of pain, erosion or exposure, and urinary problems.

CONCLUSION

For these reasons, the Court should deny Plaintiffs' motion to exclude the general causation testimony of Dr. Bruce S. Kahn.

Respectfully submitted,

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CERTIFICATE OF SERVICE

I certify that on this day, I electronically filed this document with the clerk of the court using the CM/ECF system, which will send notification of this filing to CM/ECF participants registered to receive service in this MDL.

/s/ William M. Gage

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